

CLAIMS

1. A purified and isolated DNA having a sequence selected from the group consisting of SEQ ID NO:1 through SEQ ID NO:51.

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2. A purified and isolated protein encoded by a gene whose sequence includes a sequence selected from the group consisting of SEQ ID NO:52 through SEQ ID NO:102.

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3. A purified and isolated DNA having a sequence selected from the group consisting of SEQ ID NO: 103 through SEQ ID NO: 154.

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4. A purified and isolated protein encoded by a gene sequence selected from the group consisting of SEQ ID NO: 155 through SEQ ID NO: 206.

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5. A purified and isolated protein having an amino acid sequence selected from the group consisting of SEQ ID NO:52 through SEQ ID NO:102 and SEQ ID NO:155 through SEQ ID NO:206.

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6. A method for the recombinant DNA-directed synthesis of a protein, said method comprising:  
culturing a transformed or transfected host organism containing a DNA sequence capable of directing the host organism to produce said protein under conditions such that the protein is produced, said protein exhibiting substantial homology to a protein comprising the amino acid sequence selected from the group consisting of SEQ ID NO:52 through SEQ ID NO:102 or SEQ ID NO:155 through SEQ ID NO:206.

7. The method of claim 6, wherein the host organism is transfected with a recombinant eukaryotic expression vector.

8. The method of claim 7, wherein the host organism is a eukaryotic cell.

9. A recombinant expression vector comprising a DNA sequence selected from the group consisting of SEQ ID NO:1 through SEQ ID NO:51 and SEQ ID NO:103 through SEQ ID NO:154.

10. A host organism transformed or transfected with a recombinant expression vector according to claim 9.

11. A method of detecting antibodies against HCV, said method comprising:

- (a) contacting a biological sample with at least one protein of claim 5 to form an immune complex with the antibodies; and
- (b) detecting the presence of the immune complex.

12. The method of claim 11 wherein the biological sample is selected from the group consisting of serum, saliva or lymphocytes or other mononuclear cells.

13. The method of claim 11, wherein the recombinant protein is bound to a solid support.

14. The method of claim 11, wherein the immune complex is detected using a labeled antibody.

15. A hepatitis C virus kit comprising: at least one protein comprising an amino acid sequence selected from the group consisting of: SEQ ID NO:52 through SEQ ID NO:102

° and SEQ ID NO:155 through SEQ ID NO:206.

16. A composition comprising at least one recombinant protein of claim 5 and an excipient, diluent or carrier.

5 17. A composition comprising an expression vector capable of directing host organism synthesis of a protein having an amino acid sequence selected from the group consisting of SEQ ID NO: 52 through SEQ ID NO: 102 and SEQ ID NO: 155 through SEQ ID NO: 206.

10 18. A method of preventing hepatitis C infection, comprising administering the composition of claim 16 or 17 to a mammal in an effective amount to stimulate the production of protective antibody.

15 19. A vaccine for immunizing a mammal against hepatitis C infection, comprising at least one protein according to claim 5 in a pharmacologically acceptable carrier.

20 20. A vaccine for immunizing a mammal against hepatitis C infection, said vaccine comprising an expression vector capable of directing host organism synthesis of a protein having an amino acid sequence  
25 selected from the group consisting of SEQ ID NO:52 - SEQ ID NO:102 and SEQ ID NO:155 - SEQ ID NO:206.

30 21. A method for detecting the presence of the hepatitis C virus via a reverse transcription-polymerase chain reaction, said method comprising amplifying an HCV reverse transcription product by polymerase chain reaction using universal primers.

35 22. The method of claim 21, wherein said universal primers are deduced from universally conserved

23. Substantially isolated and purified universal primers, wherein said primers have nucleic acid sequences derived from universally conserved nucleotide domains found in SEQ ID NO:1 through SEQ ID NO:51, in SEQ ID NO:103 through SEQ ID NO:154 and in consensus sequences showing Figures 1A-H and 6A-K.

24. A diagnostic kit for use in detecting the presence of hepatitis C virus in a biological sample, said kit comprising at least two universal primers according to claim 22.

25. A diagnostic kit for use in detecting the presence of hepatitis C virus is a biological sample, said kit comprising at least one nucleic acid sequence selected from the group consisting of SEQ ID No:1-51 or SEQ ID No:103-154.

26. A method for determining the genotype of a hepatitis C virus, said method comprising:

amplifying reverse transcription products of RNA via polymerase chain reaction using genotype-specific amplification primers deduced from genotype-specific nucleotide domains found in SEQ ID NO:1 through SEQ ID NO:51, in SEQ ID NO:103 through SEQ ID NO:154, or in consensus sequences shown in Figures 1A-H and 6A-K.

27. A method for determining the genotype of a hepatitis C virus, said method comprising:

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- (a) amplifying RNA via reverse transcription-polymerase chain reaction to produce amplification products;
  - (b) contacting said products with at least one sequence shown in SEQ ID NO:1 through SEQ ID NO:51 and SEQ ID NO:103 through SEQ ID NO:154; and
  - (c) detecting complexes of said product which bind to said nucleic acid sequence.

10 28. A method for determining the genotype of a hepatitis C virus, said method comprising:

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- (a) amplifying RNA via reverse transcription-polymerase chain reaction to produce amplification products;
  - (b) contacting said products with at least one genotype-specific oligonucleotide; and
  - (c) detecting complexes of said products which bind to said oligonucleotide(s).
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25 29. The method of claims 27 or 28, wherein said amplification of step (a) uses universal primers deduced from universally conserved nucleotide domains found in SEQ ID NO:1 through SEQ ID NO:51, in SEQ ID NO:103 through SEQ ID NO:154, or in consensus sequences shown in Figures 1A-H and 6A-K.

30 30. The method of claim 28, wherein said genotype-specific oligonucleotide of step (b) is a nucleic acid sequence deduced from genotype-specific nucleotide domains found in SEQ ID NO:1 through SEQ ID NO:51 and SEQ ID NO:103 through SEQ ID NO:154, or in consensus sequences shown in Figures 1A-H and 6A-K.

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31. Substantially isolated and purified genotype-specific oligonucleotides, wherein said oligonucleotides have nucleic acid sequences deduced from genotype-specific nucleotide domains found in SEQ ID NO:1 through SEQ ID NO:51, in SEQ ID NO:103 through SEQ ID NO:154, or in consensus sequences shown in Figures 1A-H and 6A-K.

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10 32. Substantially purified and isolated genotype-specific peptides having amino acid sequences deduced from a genotype-specific amino acid domains located in SEQ ID NO:52 through SEQ ID NO:102, in SEQ ID NO:155 through SEQ ID NO:206, or in consensus sequences shown in Figures 2A-H and 7A-K.  
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15 33. A method of detecting antibodies specific for a single genotype of HCV, said method comprising:  
20 (a) contacting a biological sample with at least one peptide of claim 32 to form an immune complex with the antibodies, and  
(b) detecting the presence of the immune complex.

25 34. The method of claim 33, wherein the biological sample is selected from the group consisting of serum, saliva or lymphocytes or other mononuclear cells.

35 35. The method of claim 33, wherein said peptide is bound to a solid support.

30 36. The method of claim 33, wherein the immune complex is detected using a labelled antibody or antigen.

35 37. A kit for use in detecting antibodies specific for a single genotype of HCV, said kit comprising:

- ° at least one peptide selected from the genotype-specific peptides of claim 32.

38. Substantially purified and isolated universal peptides having amino acid sequences deduced from universally conserved amino acid domains found in SEQ ID NO:52 through SEQ ID NO:102, in SEQ ID NO:155 through SEQ ID NO:206, or in consensus sequences shown in Figures 2A-H and 7A-K.

10 39. A method of detecting antibodies against all genotypes of HCV, said method comprising:

- 15 (a) contacting a biological sample with at least one peptide of claim 38 to form an immune complex with the antibodies, and  
(b) detecting the presence of the immune complex.

20 40. The method of claim 39, wherein the biological sample is selected from the group consisting of serum, saliva or lymphocytes or other mononuclear cells.

25 41. The method of claim 39, wherein said peptide is bound to a solid support.

42. The method of claim 39, wherein the immune complex is detected using a labelled antibody or antigen.

30 43. A composition comprising at least one peptide of claim 32 and an excipient, diluent or carrier.

44. A composition comprising at least one peptide of claim 38 and an excipient, diluent or carrier.

35 45. A method of preventing hepatitis C

- ° infection, comprising administering the composition of claims 43 or 44 to a mammal in an effective amount to stimulate production of a protective antibody.

- 5 46. A vaccine for immunizing a mammal against hepatitis C infection, comprising at least one peptide according to claims 32 or 38 in a pharmaceutically acceptable carrier.

- 10 47. A composition comprising at least one expression vector capable of directing host organism synthesis of a genotype-specific peptide having amino acid sequence deduced from a genotype-specific amino acid domain located in SEQ ID NO:52 - SEQ ID NO:102, and SEQ ID NO:155 - SEQ ID NO:206, or in consensus sequences shown in figures 2A-H and 7A-K.

- 15 48. A composition comprising at least one expression vector capable of directing host organism synthesis of a universal peptide having amino acid sequence deduced from universally conserved amino acid domains found in SEQ ID NO:52 - SEQ ID NO:102, and SEQ ID NO:155 - SEQ ID NO:206, or in consensus sequences shown in figures 2A-H and 7A-K.

- 25 49. A method of preventing hepatitis C infection, comprising administering the composition of claims 47 or 48 to a mammal in an effective amount to stimulate production of a protective antibody.

- 30 50. A vaccine for immunizing a mammal against hepatitis C infection, said vaccine comprising at least one expression vector capable of directing host organism synthesis of a geno-type specific peptide having amino acid sequence deduced from a geno type-specific amino acid domain located in SEQ ID NO:52 - SEQ ID NO:102, and SEQ ID
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- ° NO:155 - SEQ ID NO:206, or in consensus sequences shown in figures 2A-H and 7A-K.

51. A vaccine for immunizing a mammal against hepatitis C infection, comprising at least one expression  
5 vector capable of directing host organism synthesis of a universal peptide having amino acid sequence deduced from universally conserved amino acid domain found in SEQ ID NO:52 - SEQ ID NO:102, and SEQ ID NO:155 - SEQ ID NO:206, or in consensus sequences shown in figures 2A-H and 7A-K.

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52. Anti-HCV core antibodies having specific binding affinity for core protein of a single genotype of HCV.

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53. Anti-HCV envelope 1 antibodies having specific binding affinity for envelope 1 protein of a single genotype of HCV.

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54. The antibodies of claims 52 or 53 wherein said antibodies are monoclonal antibodies.

55. A method of detecting core protein specific for a single genotype of HCV, said method comprising:

- 25 (a) contacting a biological sample with at least one antibody of claim 52 to form an immune complex with said core protein, and  
(b) detecting the presence of the immune complex.

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56. A method of detecting E1 protein specific for a single genotype of HCV, said method comprising:

- 35 (a) contacting a biological sample with at least one antibody of claim 53 to form an immune complex with said E1 protein;

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and

- (b) detecting the presence of the immune complex.

57. The methods of claims 55 or 56, wherein the  
5 biological sample is selected from the group consisting of  
serum, saliva lymphocytes or other mononuclear cells and  
liver.

58. The method of claims 55 or 56, wherein said  
10 antibody is bound to a solid support.

59. A method of detecting antibodies against all  
genotypes of HCV, said method comprising:

- 15 → (a) contacting a biological sample with at  
least one universal peptide of claim 38  
to form an immune complex with said  
antibodies; and
- (b) detecting the presence of the immune  
complex.

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